

REMARKS

Claims 1 and 3-11 are pending in this application. Claim 2 has been canceled without prejudice or disclaimer. Claim 1 has been amended for the sole reason of advancing prosecution.

Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Independent claim 1 has been amended to recite "[a] patch, comprising: a backing layer; an adhesive layer disposed on the backing layer and compounded with an adhesive base agent, the adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups, a rubber polymer, and a non-self-adhesive basic nitrogen-including polymer comprising a basic nitrogen; and pergolide and/or a pharmaceutically acceptable salt thereof, wherein the acrylic polymer and the rubber polymer are present in a weight ratio of from 1:1 to 1:9 by weight, and wherein a weight ratio of both of the acrylic polymer and the rubber polymer to the basic nitrogen-including polymer is from 9:1 to 1:1 by weight." Support for claim 1, as amended, can be found throughout the specification and claims as originally filed. Claims 3-11 depend, either directly or indirectly, from claim 1.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

- I. At pages 6-9 of the Official Action, claims 1 and 3-11 have been rejected under 35 USC § 103(a) as being unpatentable over Chono et al. (EP 1 201 232) in view of Hirano et al. (US Patent Application Publication No. 2002/0102290) and in further view of Terahara et al. (CA2428181).*

The Examiner asserts that it would have been obvious to modify the cited references to arrive at the presently claimed subject matter. In particular, the Examiner asserts that Chono et al. describe the use of acrylic polymers, e.g., 2-ethylhexyl acrylate and vinyl acetate, which contain some carboxyl groups. However, the Examiner asserts that the acrylic polymers described in Chono et al. are considered to be **substantially free** of carboxyl and hydroxyl groups and thus, fall within the scope of the presently pending claims. Further, the Examiner asserts that it would have been obvious to modify the adhesive pharmaceutical preparations described in Chono et al. in view of Hirano et al. and Terahara et al. to arrive at the presently claimed subject matter.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the

relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants respectfully submit that a *prima facie* case of obviousness has not been established because, whether taken alone or in combination, none of the cited references teach or suggest every element of the presently pending subject matter.

Independent claim 1 is directed to a patch, comprising: a backing layer; an adhesive layer disposed on the backing layer and compounded with an adhesive base agent, the adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups, a rubber polymer, and a non-self-adhesive basic nitrogen-including polymer comprising a basic nitrogen; and pergolide and/or a pharmaceutically acceptable salt thereof, wherein a weight ratio of the acrylic polymer to the rubber polymer is from 1:1 to 1:9 by weight, and wherein a weight ratio of both of the acrylic polymer and the rubber polymer to the basic nitrogen-including polymer is from 9:1 to 1:1 by weight. Claims 3-11 depend, either directly or indirectly, from claim 1.

In contrast to the presently pending subject matter, Chono et al. is directed to a patch formulation comprising an adhesive layer, a backing layer for supporting the

adhesive layer and a release liner on the adhesive layer, wherein the adhesive layer comprises a basic drug, an organic acid and an organic acid salt. See Chono et al. at paragraph [0014].

However, unlike the presently claimed subject matter, Chono et al. do not teach or suggest a patch, comprising: a backing layer; an adhesive layer disposed on the backing layer and compounded with an adhesive base agent, ***the adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups***, a rubber polymer, and a non-self-adhesive basic nitrogen-including polymer comprising a basic nitrogen; and pergolide and/or a pharmaceutically acceptable salt thereof, wherein a weight ratio of the acrylic polymer to the rubber polymer is from 1:1 to 1:9 by weight, and wherein a weight ratio of both of the acrylic polymer and the rubber polymer to the basic nitrogen-including polymer is from 9:1 to 1:1 by weight, by weight, as presently claimed.

In contrast, Chono et al. describe the use of a copolymer of at least two monomers selected from the group consisting of 2-ethylhexyl acrylate, vinyl acetate, methacrylates, methoxyethyl acrylate and acrylic acid. See Chono et al. at paragraph [0030]. However, Chono et al. do not teach or suggest a patch comprising an ***adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups***, as presently claimed. Accordingly, Chono et al. do not teach or suggest every element of the presently claimed subject matter.

Hirano et al. do not remedy the deficiencies of Chono et al. Hirano et al. is directed to a transdermal preparation comprising at least three layers, including a drug-impermeable backing layer, a drug storage layer provided between the backing layer

and a drug release layer containing a serotonin receptor antagonist, and a drug release layer comprising a pressure-sensitive adhesive layer. See Hirano et al. at the abstract.

However, like Chono et al., Hirano et al. do not teach or suggest a patch comprising an **adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups**, as presently claimed. In contrast, Hirano et al. describe that an acrylic adhesive may be used simultaneously with a rubber elastomer. However, nowhere in Hirano et al. is an adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups either taught or suggested. Accordingly, whether taken alone or in combination, none of Chono et al. and Hirano et al. teach or suggest each and every element of the presently claimed subject matter, as required by *In re Wilson*.

Terahara et al. do not remedy the deficiencies of Chono et al. and Hirano et al. Terahara et al. is directed to an adhesive preparation comprising a polymer having amino groups, a drug, and a carboxylic acid. See Terahara et al. at page 5, second paragraph.

However, like Chono et al. and Hirano et al., Terahara et al. do not teach or suggest a patch comprising an **adhesive base agent comprising a self-adhesive acrylic polymer having no carboxyl or hydroxyl groups**, as presently claimed. In contrast, in Terahara et al., at Examples 3, 5 and 6, describe the use of an acrylic polymer, i.e., Duro-Tak387-2287, which contains carboxyl groups, which is in clear contrast to the presently claimed subject matter. Further, Applicants note that only Examples 5 and 6 in Terahara et al. describe the use of an acrylic polymer **and** a rubber polymer. However, Examples 5 and 6 in Terahara et al. both describe the use of an

acrylic polymer having carboxyl groups, which is expressly excluded from the presently claimed subject matter. Accordingly, whether taken alone or in combination, none of Chono et al., Hirano et al. and Terahara et al. teach or suggest each and every element of the presently claimed subject matter, as required by *In re Wilson*.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination, the cited art does not render the presently pending claims obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At pages 10-13 of the Official Action, claims 1 and 5-8 have been provisionally rejected under the Judicially Created Doctrine of Obviousness-Type Double Patenting.

The Official Action states that claims 1 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8 and 12 of copending U.S. Patent Application Serial No. 10/469,612 (hereinafter "the '612 Application"). The Examiner acknowledges that claims 1, 8 and 12 of the '612 Application fail to teach or suggest a weight ratio of the content of the acrylic polymer to the content of the rubber polymer being from 1:1 to 1:9, and a weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer being from 9:1 to 1:1, as presently claimed. However, the Examiner asserts that it would have been obvious to modify the weight ratios in order to arrive at the presently claimed subject matter.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time as the Examiner indicates there is successful resolution of the claim rejections noted above. Applicants, at that time, will either address the rejection or file a terminal disclaimer over co-pending U.S. Patent Application No. 10/469,612.

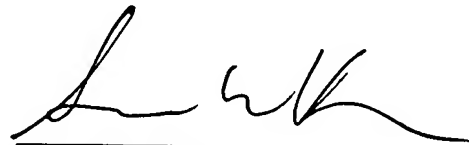
CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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Date: June 8, 2009

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